IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	**Jacob Richter et al.**	**Confirmation No.:**	**1194**
Serial No.:	**09/864,389**	**Group Art Unit:**	**3773**
Filed:	**May 25, 2001**	**Examiner:**	**Bui, Vy Q.**
Title:	**LONGITUDINALLY FLEXIBLE STENT**		

AMENDED APPEAL BRIEF UNDER 37 C.F.R. §41.37

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Notification of Non-Compliant Appeal Brief dated December 30, 2009, applicant respectfully submits this amended summary of claimed subject matter in accordance with 37 CFR 41.37(c)(1)(v). Further to MPEP 1205.03, the present submission contains only the amended summary of claimed subject matter. Favorable reconsideration and allowance of this application is respectfully requested in view of the appeal brief submitted on December 4, 2009, amended as follows.

V. Summary of Claimed Subject Matter

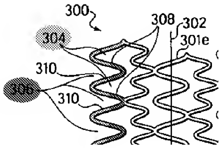
V.A. Claim 1

Independent claim 1 recites a stent formed by first and second loop containing sections that are each joined directly, without intervening materials, to third loop containing sections occurring between each first and second loop containing section.

Said loop containing sections are formed from single, continuous, sinusoidal patterns and include struts. The first and second loop containing sections extend around the entire circumference of the stent. The loops of the first and second loop containing sections occur at the same frequency, whereas the loops of the third loop containing sections occur at a higher frequency than the loops of the first and second loop containing sections. In addition, the struts of the first and second loop containing sections are wider than the struts of the third loop containing sections. Lastly, the loops in the first, second and third loop containing sections cooperate such that the loops of the third loop containing section contribute to the elongating or shortening of the stent when flexed.

The specification as originally submitted describes the arrangement of “first”, “second” and “third loop containing sections” on page 12, lines 13-20 with reference to Figures 3 and 5. As indicated on page 12, lines 13-16, the specification refers interchangeably to “vertical loop containing sections” and “vertical sinusoidal patterns.” Thus, the description of a “vertical sinusoid” on page 8, lines 9-17 of the specification also applies to “loop containing section”, as that term is used in claim 1. Page 8, lines 11-16 of the specification describes a “vertical sinusoid” / “loop containing section” as “a periodic pattern which varies positively and negatively symmetrically about an axis” such that a right-opening loop 304 is joined to a left-opening loop 306 with a common member 310 between them, followed by another right-opening loop 304 also joined by a common member 310. In other words, a “loop containing section” is formed by a repeating sequence of loops 304 opening “to the right” that are each joined to loops 306

opening “to the left”, alternating along a circumferential axis as illustrated in Figure 3, shown below:



The description of a “loop containing section” on page 8, lines 9-17 and page 12, lines 13-22 of the specification therefore corresponds with the language recited by claim 1 that a “loop containing section” is formed of a “single, continuous, generally sinusoidal pattern.”

The specification further describes “first”, “second” and “third loop containing sections” with reference to axis lines 302 and 305 on page 12, lines 16-20 of the specification as illustrated in Figure 3, shown below:

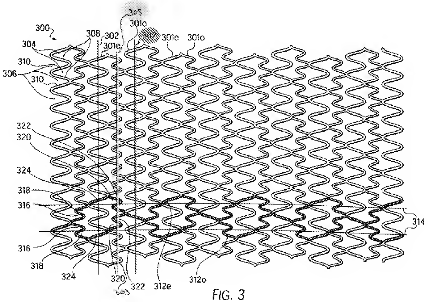


FIG. 3

Thus, for example, a second loop containing section occurs as a periodic pattern varying positively and negatively about an axis 302 (orange), while a third loop containing section occurs as a periodic pattern varying positively and negatively about an axis 305 (blue). Notably, the circumferential axes 302 and 305 extend along the entire circumferential length of the stent; thus, as depicted in linear form by Figure 3, the loop containing sections are understood by one skilled in the art to extend around the entire circumference of the stent once formed. As illustrated in Figure 3 and described on page 12, lines 18-20 of the specification, the third loop containing section formed along axis 305 has loops that occur at a higher frequency than the loops of the second loop containing section formed along axis 302.

With regard to the contribution of the third loop containing sections to the elongating and shortening of the cells when the stent is flexed, the specification describes the cooperation between elements of the stent on page 11, line 23 to page 12, line 3, and on page 13, line 24 to page 14, line 19 of the specification. On page 11, line 30 to page 12, line 3, the specification describes "fifth, sixth, seventh, eighth, ninth, and tenth members" with reference to Figure 4 that are "optimized predominantly to enable longitudinal flexibility" relative to "first, second, third, and fourth members", which by contrast are "optimized predominantly to enable sufficient resistance to radial compression." As noted on page 10, lines 11-12 of the specification, Figure 4 is an "expanded view" of the stent illustrated in Figure 3, and one skilled in the art will recognize in Figure 4 the fifth, sixth, seventh, eighth, ninth, and tenth members make up the higher-frequency "third loop containing sections" and the first, second, third, and fourth members make up the lower-frequency "first" and "second loop containing

sections” wherein these latter loop containing sections have struts of greater width, as shown below:

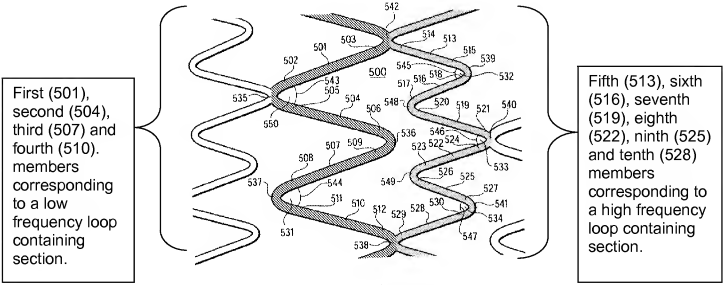


FIG. 4

Thus, the application contemplates higher frequency third loop containing sections (blue) contributing to the overall flexibility of the stent relative to the first and second loop containing sections (orange), which by comparison provide radial strength to the stent. The contribution of third loop containing sections upon flexing of the stent is further described by the specification on page 13 line 24 to page 14, line 19, with reference to Figure 15 as shown below:

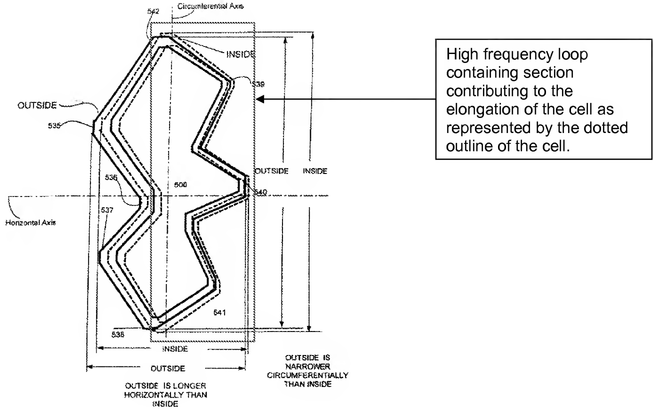
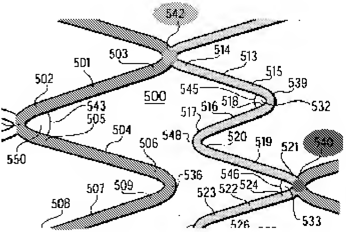


Figure 15 indicates the deformation of the cell following the flexing of the stent by dotted outline, such that the high frequency loop containing section deforms to elongate the cell. Thus, as recited by claim 1, the specification contemplates components of the high frequency third loop containing section contribute to the elongating or shortening of the stent when flexed.

Further, as noted by the specification on page 12, lines 23-24, "the higher frequency loop containing elements are smaller in width." As discussed on page 12, line 28 to page 13, line 10, the novel feature of "high frequency vertical patterns of smaller width" results in elements of the stent having a lower maximal strain without non-elastic deformation. The application specifically identifies the smaller width in the high frequency bands as advantageous for increased flexibility of the invented stent,

aiding both in “conforming better to the curved lumen” as well as “bend[ing] with each beat of the heart . . . for many years without breaking.”

With regards to the limitation recited in claim 1 that the third loop containing section is connected directly “without intervening materials” to the first and second loop containing sections, the specification on page 10, lines 27-28 and on page 11, line 2 clearly identifies “junction point[s]” 540 and 542 with regard to Figure 4 – which, as noted above, provides an “expanded view” of the stent illustrated by stent 3 -- where a higher frequency loop containing section connects directly to a lower frequency loop containing section, as shown below:



Thus, “junction point” 540 (red) and “junction point” 542 (green) represent the points at which a higher-frequency “third loop containing section” connects directly to a lower-frequency “first or second loop containing section” without intervening material.

Accordingly, the limitations recited by claim 1 correspond with the stent depicted by Figure 3 and described throughout the specification.

V.B. Claim 6

Independent claim 6 recites a stent formed by first and second circumferential bands, each formed of a single, continuous, generally sinusoidal pattern of loops extending around the entire circumference of the stent. The first and second circumferential bands alternate along the longitudinal axis of the stent for at least two repetitions and are periodically coupled directly without intervening materials to form cells. The loops of the second circumferential bands occur at a higher frequency than the loops of the first circumferential band, and the loops of the first circumferential band have struts that are wider than the struts of the loops of the second circumferential band. The loops of the first and second circumferential bands are disposed and adapted to cooperate so that the second circumferential band contributes more to deformation during flexing than the first circumferential band.

One skilled in the art will recognize that a "circumferential band", particularly as described by claim 6 as a "single, continuous, generally sinusoidal pattern of loops", corresponds with the "vertical sinusoid" disclosed in the specification on page 8, lines 9-16 and on page 12, lines 13-20, as discussed above. Furthermore, Figure 3 clearly illustrates the stent as recited by claim 6, wherein first circumferential bands having loops occurring at a lower frequency alternate with second circumferential bands having loops occurring at a higher frequency, wherein the first circumferential bands are coupled directly to second circumferential bands without intervening materials to form cells, as shown below:

Cell formed by coupling of first and second circumferential bands

First circumferential bands, each formed of a single, continuous, generally sinusoidal pattern of loops occurring at a first frequency

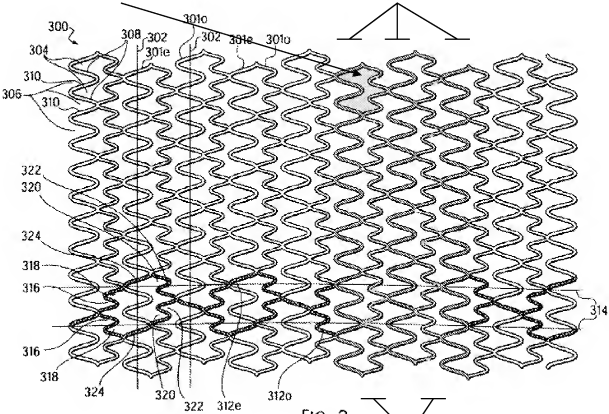


FIG. 3

Second circumferential bands, each formed of a single, continuous, generally sinusoidal pattern of loops occurring at a second frequency higher than the first, occurring between adjacent first circumferential bands and coupled thereto without intervening materials

Thus, as illustrated in Figure 3, the application discloses a stent formed by first circumferential bands (orange) coupled directly with second circumferential bands (blue) without intervening materials, wherein the first and second circumferential bands are each formed of a single, continuous, generally sinusoidal pattern of loops, as recited by claim 6.

With regard to the relative contribution of the second circumferential bands to deformation during flexing of the stent, the specification describes the cooperation between elements of the stent on page 11, line 23 to page 12, line 3 and on page 13, line 24 to page 14, line 19. Therein, the application contemplates high frequency second circumferential bands having greater flexibility relative to the low frequency first circumferential bands. For example, on page 11, line 23 to page 12, line 3, the specification describes “fifth, sixth, seventh, eighth, ninth, and tenth members” with reference to Figure 4 that are “optimized predominantly to enable longitudinal flexibility” relative to “first, second, third, and fourth members”, which by contrast are “optimized predominantly to enable sufficient resistance to radial compression.” As noted on page 10, lines 11-12 of the specification, Figure 4 is an “expanded view” of the stent illustrated in Figure 3, and one skilled in the art will recognize that the fifth, sixth, seventh, eighth, ninth, and tenth members correspond to a second circumferential band while the first, second, third, and fourth members correspond to a first circumferential band. Further, on page 13, line 24 to page 14, line 19 with reference to Figure 15, the specification describes the behavior of a cell when the stent is flexed. As shown above, the high frequency band of loops naturally deforms due to its relatively greater flexibility when the stent is flexed. Thus, as recited by claim 6, the specification contemplates high frequency circumferential bands of loops having relatively greater flexibility and thereby contributing more than the low frequency circumferential bands to the deformation of the stent when flexed.

Lastly, as noted by the specification on page 12, lines 23-24, “the higher frequency loop containing elements are smaller in width.” In the context of claim 6, the

"higher frequency loop containing elements" correspond with second circumferential bands, with lower frequency loop containing elements corresponding to first circumferential bands. The specification therefore describes first circumferential bands having struts that are wider than the struts of the second circumferential bands as recited by claim 6.

Accordingly, the limitations recited by claim 6 correspond with the stent depicted by Figure 3 and described throughout the specification.

V.C. Claim 49

Independent claim 49 recites a stent consisting essentially of first and second loop containing sections each having loops occurring at the same frequency (see page 12, lines 16-18 of the specification) with the loops of the second loop containing sections being 180° out of phase with the loops of the first loop containing sections (see page 8, lines 25-29 of the specification), and a third loop containing section having loops occurring at a higher frequency than the loops of the first and second loop containing sections (see page 12, lines 18-20 of the specification). At least one of the first and second loop containing sections as well as the third loop containing sections are formed of a single, continuous, generally sinusoidal pattern of loops (see page 8, lines 9-17 of the specification). The third loop containing sections are disposed between each of the first and second loop containing sections to form a consecutively repeating pattern for at least two repetitions; further, the third loop containing sections are joined alternately to the first and second loop containing sections forming a pattern of uniform cells (see page 12, lines 20-22 of the specification). Finally, the first, second

and third loop containing sections have struts, wherein the struts of the first and second loop containing sections are wider than the struts of the third loop containing sections (see page 12, lines 23-24 of the specification).

The understanding of a “first”, “second”, and “third loop containing section” is described in detail in section V.A. Of note, claim 49 recites a stent consisting essentially of said first, second and third loop containing sections wherein at least one of the first or second loop containing sections are single, continuous and generally sinusoidal, and the third loop containing section is also single, continuous and generally sinusoidal as shown below in Figure 3:

First loop containing sections formed of a single, continuous and generally sinusoidal pattern.

Second loop containing section also formed of a single, continuous and generally sinusoidal pattern and having loops that are 180° out-of-phase with the loops of the first loop containing sections.

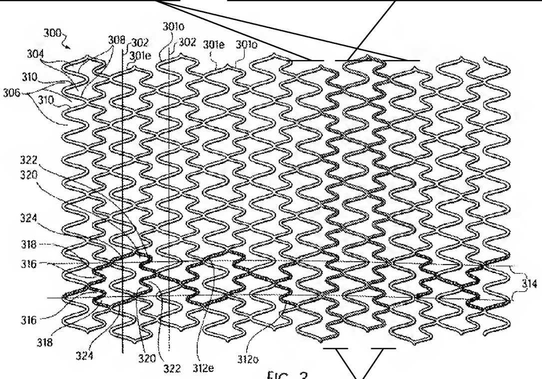


FIG. 3

Third loop containing sections, each formed of a single, continuous and generally sinusoidal pattern, disposed in the generally circumferential space between each first and second loop containing sections to form a pattern along the longitudinal axis of the stent.

As is well understood, “consisting essentially of” limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original); see also MPEP §2111.03. Therefore, insofar as the third loop containing section must be a single, continuous, generally sinusoidal pattern of loops, and further occurs between each of the first and second loop containing sections (at least one of which must also be a single, continuous, generally sinusoidal pattern of loops) and connects together with them to form a uniform pattern of cells, there necessarily is no intervening material between the third loop containing section and either the first or the second loop containing sections, as this would necessarily affect the basic and novel characteristics of the claimed stent (as discussed in more detail in section VII.G, infra). Likewise, the placement of high frequency third loop containing sections between first and second loop containing sections – said first and second loop containing sections having struts that are wider than the struts of the third loop containing section – contributes to the basic and novel characteristics of the stent in that, as taught by the present application, e.g. on page 12, line 28 to page 13, line 10 of the specification, the third loop containing sections contribute to overall flexibility whereas the first and second loop containing sections provide increased radial resistance. One skilled in the art will recognize the advantage to having low frequency loop containing sections having increased radial resistance at either end of the stent (as well as located throughout the middle of the stent) with high frequency loop containing sections having increased flexibility there between. The low frequency loop containing sections having wider and longer struts are ideally suited to

provide radial strength. The high frequency loop containing sections are suited for flexibility because the higher number of loops provides that each loop has a lower maximal strain allowing for long-term bending without breakage.

Finally, with regard to the limitation recited in claim 49 that the loops of the second loop containing section are 180° out of phase with the loops of the first loop containing section, page 8, lines 25-29 of the specification specifically references vertical meander patterns – understood by one skilled in the art as synonymous with "loop containing sections" (<u>see</u> page 12, lines 13-20 of the specification), as discussed above – "in odd and even (*o* and *e*) versions which are 180° out of phase with each other" with reference to Figure 3. As shown below, Figure 3 clearly illustrates first and second loop containing sections, in which an adjacent second loop containing section has loops that are 180° out of phase with the loops of a first loop containing section.

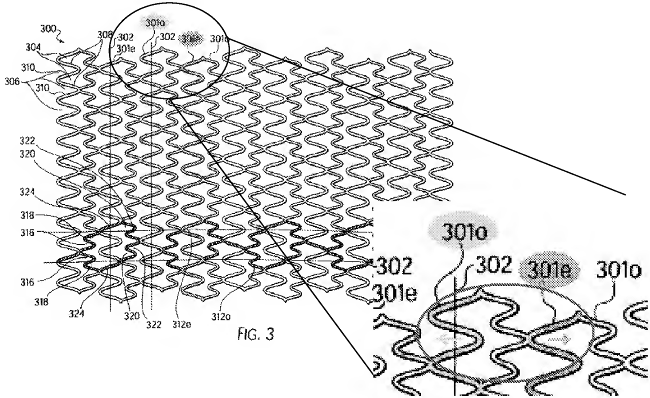


FIG. 3

Thus, as described on page 8, lines 25-29 of the specification and illustrated in Figure 3, claim 49 recites a first loop containing section 301o (blue) adjacent a second loop containing section (301e) having loops which are 180° out of phase with each other.

Accordingly, the limitations recited by claim 49 correspond with the stent depicted by Figure 3 and described throughout the specification.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. 50-4387, Order No. 92077.003.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. 50-4387, Order No. 92077.003.

Respectfully submitted,
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Dated: February 1, 2010

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